

# Pregnancy after Novasure® Endometrial Ablation: Two Cases and a Literature Survey

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## Abstract

NovaSure® endometrial ablation is a successful therapy for patients with heavy menstrual bleeding who do not want to preserve fertility. However, endometrial ablation is not a contraceptive treatment. We report two cases of pregnancy after NovaSure® endometrial ablation. Case 1 is a pregnancy in a 44-year old woman. An elective abortion was performed at 9 5/7 weeks of gestational age. Case 2 is a pregnancy in a 41-year old woman which was complicated by a placenta increta. She underwent a caesarean section followed by a hysterectomy at 35 1/7 weeks of gestational age. Data on pregnancies after NovaSure® are limited. So far, 26 case reports of pregnancy after NovaSure® could be identified. Data were available for merely 11 cases. Due to the high incidence of potentially life-threatening complications, contraception is essential for all women who undergo NovaSure® endometrial ablation.

**Keywords:** Pregnancy, NovaSure®, Endometrial ablation, Contraception, Abnormal placenta adherence

## Introduction

Endometrial ablation is a successful therapy for patients with heavy menstrual bleeding who do not want to preserve fertility [1]. Currently, second-generation endometrial ablation techniques are preferred since they are technically easier, with similar patient satisfaction scores compared to hysteroscopy-based methods such as transcervical resection of endometrium (TCRE) [2]. Moreover, second-generation endometrial ablation techniques are more effective compared to first-generation techniques regarding the presence of amenorrhea two years after treatment [3].

NovaSure® is a second-generation endometrial ablation technique which was introduced in 2002. NovaSure® ablates the endometrium by using bipolar radiofrequency [4]. With this technique more women report amenorrhea after treatment compared with other endometrial ablation techniques [5]. Twelve-month amenorrhea rates of patients treated by NovaSure® endometrial ablation ranged between 43 and 56% [6]. These good results are caused by the effectiveness of bipolar radiofrequency at destroying the endometrium. However, endometrium is extremely able to regenerate, and hence focal regeneration of remaining endometrium could make the uterus susceptible for pregnancy [7].

While much is known about pregnancies occurring after endometrial ablation, there are only a few publications about the incidence of pregnancy after NovaSure® endometrial ablation and the need for contraception after this procedure [7-16].

Therefore, we present two cases of pregnancy after a NovaSure® endometrial ablation and an update of the most recent literature on pregnancies after endometrial ablation in general and for NovaSure® endometrial ablation in particular.

## Patients and Methods

### Case 1

A 42-year-old woman was presented at the outpatient clinic of the TweeSteden hospital with heavy menstrual bleeding and dysmenorrhea after unsuccessful treatment with a levonogestrel (LNG) intra-uterine device (IUD). Her obstetrical history was unremarkable showing three uncomplicated vaginal deliveries. At gynecological ultrasound an enlarged fibroid uterus was seen with one anterior subserosal myoma of 4-5 cm. Both endometrial ablation and hysterectomy were offered as therapeutic options for this patient. She preferred the NovaSure® endometrial ablation.

NovaSure® endometrial ablation was performed under general anesthesia. The procedure went uneventfully. Afterwards the patient was counseled to use contraception, as the NovaSure® does not prevent pregnancy. At the follow-up visit after 4 weeks, the patient reported regular periods with significantly less blood loss. Although dysmenorrhea was still present, she was satisfied with the result of the procedure.



Two years after NovaSure® endometrial ablation she presented with irregular bleeding. Gynecological examination demonstrated a myoma in the anterior wall of 7 x 5 cm, measured by transvaginal sonography. The gynecologist recommended a hysterectomy. However, prior to the operation, she presented with amenorrhea. On subsequent transvaginal sonography a vital intra-uterine pregnancy was observed and dated 9 weeks and 5 days gestational age.

She requested an elective abortion. Under general anesthesia, a successful, uneventful procedure was performed followed by the insertion of a LNG-IUD. Because of the need for a more definitive form of contraception, a hysteroscopic Essure micro-insert sterilization was subsequently performed in an office setting. During this procedure both devices could be placed and the endometrial cavity appeared completely normal without any synechia that might be due to the NovaSure® endometrial ablation. During the follow-up visit both devices could be visualized on sonography.

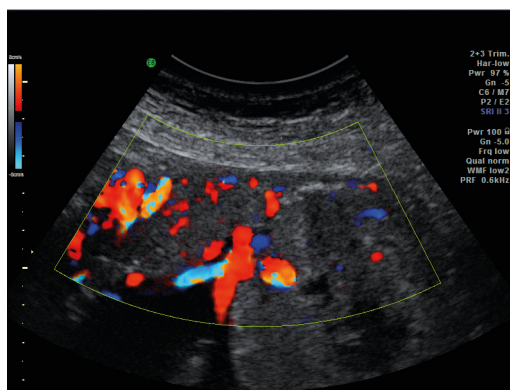
## Case 2

A 38-old-woman presented at the outpatient clinic for heavy menstrual bleeding after insufficient amelioration of her complaints with oral contraception. Her obstetric history consisted of two uncomplicated vaginal deliveries and two miscarriages. She opted for a NovaSure® endometrial ablation, which was performed under general anesthesia. The procedure was uneventful and the patient was satisfied despite the persistence of her menstrual cycle. Periods were regular with two days of minimal blood loss. She discontinued oral contraception, in retrospect stating that she was unaware of the necessity.

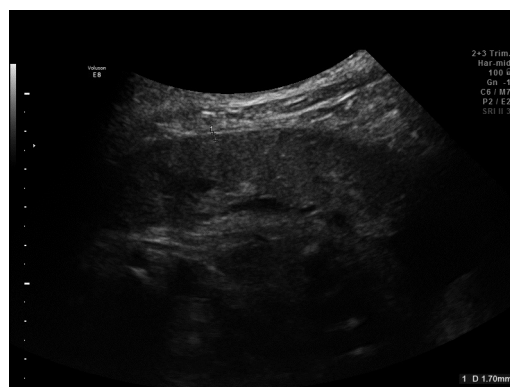
After two and a half years the patient became amenorrhoeic. However, she thought that this was the effect of NovaSure® endometrial ablation and thus she did not consult her GP or gynecologist. At 20 weeks of amenorrhea and abdominal pain the patient took a pregnancy test and the result was positive. The gestational age at ultrasound was already 22 weeks after which the couple contemplated and decided to accept the pregnancy.

At 25 weeks and 6 days gestational age she was referred to the University Hospital (Maastricht University Medical Center) with polyhydramnios to exclude esophageal atresia. During advanced ultrasound examination, no congenital abnormalities were observed. No signs of abnormal placentation were seen but the patient was advised to revisit in the third trimester of pregnancy for further evaluation of potential pathological placental invasion. At 34 weeks and 2 days gestational age the ultrasound was repeated. Multiple placental lakes were seen with a thin myometrium measuring <2 mm with a poorly recognizable transition zone and large blood vessels over the entire width of the placenta (Figure 1 and 2).

Magnetic resonance imaging confirmed the suspicion of placenta accreta or increta.



**Figure 1:** Ultrasound at 34 weeks and 2 days gestational age: Large blood vessels over the entire width of the placenta

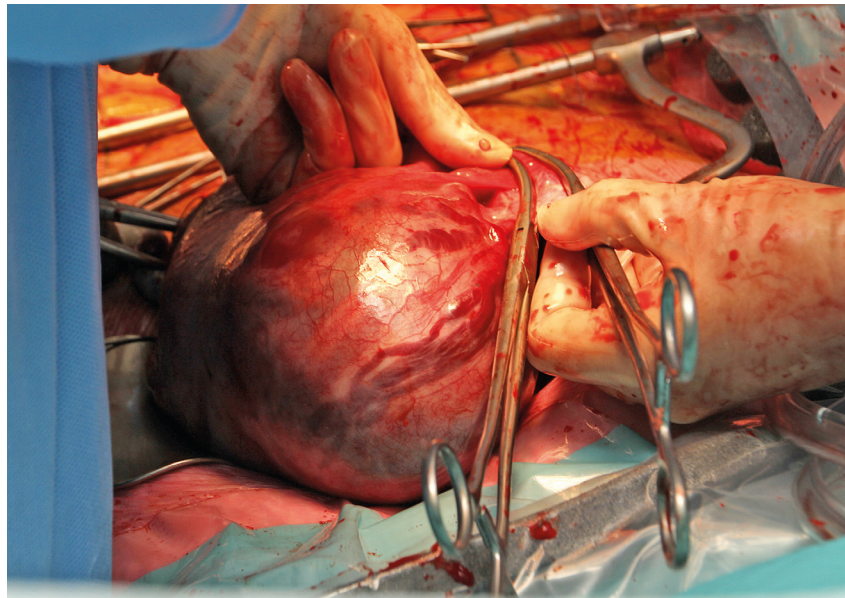


**Figure 2:** Ultrasound at 34 weeks and 2 days gestational age: Multiple placental lakes with a thin myometrium (1.7mm)



After multidisciplinary consultation, review of the literature and with the patient's approval, an elective caesarean section with hysterectomy in the same setting was planned. Betamethasone was given for fetal lung development.

At a gestational age of 35 weeks and 1 day a healthy son was born by caesarean section, with a birth weight of 2386 gram ( $\pm 50^{\text{th}}$  percentile). A hysterectomy was performed, with the placenta still in place. At macroscopic examination, a placenta percreta was observed with the placenta visible at the outer surface of the myometrium just below the serosa (Figure 3). Total blood loss was only 1500cc. The postoperative course was uncomplicated. Pathological examination revealed a myometrium thickness of 3 centimeters, but in fundo only 0.5 centimeters. The placenta grows in fundo deep into the myometrium, just onto the serosa. The final pathology concluded that there was a placenta increta.



**Figure 3:** Uterus with the placenta visible at the outer surface of the myometrium just below the serosa.

## Discussion

Because of the effectiveness of bipolar radiofrequency at destroying the endometrium, NovaSure® endometrial ablation shows higher amenorrhea rates compared to other second-generation endometrial ablation techniques [5]. However, due to the ability of the endometrium to regenerate, the chance of becoming pregnant is not ruled out. Moreover, because of the aggressive destruction of the endometrium with bipolar radiofrequency, pregnancies after NovaSure® endometrial ablation may be more complicated.

The incidence of spontaneous pregnancy after endometrial ablation is reported to be 0.24-2.41% [7-9]. However, this number is based on first-generation endometrial ablation techniques. Yin et al. reported 123 pregnancies after endometrial ablation. The majority of these cases are pregnancies after first-generation techniques (92%, 113/123). Only 8% (10/123) are pregnancies after second-generation techniques: 7 after thermal balloon, 2 after microwave and 1 after hydrothermal ablation [10]. So far, 26 case reports of pregnancy after NovaSure® have been identified. Data were available for merely 11 cases [12-16].

Possible risk factors for pregnancy after endometrial ablation are the persistence of a menstrual cycle and age at time of the ablation [7,17,18]. Xia et al. described a retrospective study including 1621 cases of all TCRE and reported 39 pregnancies (2.41%). Pregnancies were significantly more likely in women with persistent normal periods compared to women with amenorrhea: 3.2% vs. 0.3%. For this reason, it would be interesting to compare post-ablation uterine cavities to see whether there might be a difference between patients with and without pregnancy following endometrium ablation. Unfortunately, this has not yet been studied.

The age at time of the procedure is the most important risk factor for failure of endometrial ablation. Women aged over 45 years have a > 80% risk for uterine conservation at the 8-year follow-up, whereas women under the age of 40 have a 60% risk. The most common indication for hysterectomy was unacceptable vaginal bleeding [17].

Mean age at time of ablation for women with pregnancy after endometrial ablation is 35.5 years, (range 25 - 46 years) [10,18]. The majority of pregnancies occur within two years after the procedure [7,10,18]. Regarding the 11 known cases of pregnancy after NovaSure® ablation, age at conception was between 26 and 41 years and pregnancies occurred between 6 and 36 months after ablation [12-16].

Data concerning the outcome of pregnancies after endometrial ablation report a high frequency of complications. Only a minority of pregnancies after endometrial ablation will be uncomplicated and proceed until term. Yin et al. described 123 pregnancies after ablation, of which 48% (59/123) were terminated at the request of the mother. The remaining 64 pregnancies were complicated by spontaneous abortion, preterm premature rupture of the membranes, preterm birth, ectopic pregnancy, placenta adherence, perinatal mortality and maternal mortality in one case caused by uterine rupture. Therefore, the frequency of obstetric complications with pregnancy after endometrial ablation is much higher compared to the general population (Table 1) [10,19,20-22].



Complications	Pregnancy after endometrial ablation N = 64	General population*
Spontaneous abortion	28%	10.9%
Preterm premature rupture of the membranes	12%	0.5-8%
Preterm birth	31%	5-7%
Ectopic pregnancy	6.5%	2.3%
Placenta adherence	22%	0.04-0.2%
Perinatal mortality	14%	<1%
Maternal mortality	1.6%	0.01%

\*Based on frequency rates of developed countries

**Table 1:** Obstetric complications of pregnancy after endometrial ablation compared to the general population [10,19-22]

Similar results were found for pregnancy after NovaSure®. Of the available 11 cases, 1 resulted in a termination and 2 in a spontaneous abortion. The remaining 8 of the 11 cases resulted in preterm birth with a variety of other complications, including intra uterine growth restriction, preterm premature rupture of membranes, vasa praevia, abnormal placenta adherence reported in 4 cases and uterine rupture reported in 3 cases. In conclusion, none of the available cases resulted in a spontaneous labor at term [12-16]. The high placenta adherence rate, which is described in half of the cases, is particularly notable. This could result in life-threatening complications, such as uterine rupture, hysterectomy, postpartum hemorrhage, pre-term birth, perinatal mortality and maternal mortality, which is reported in 7% of the placenta percreta based on 8 cases [18,22-25].

The Dutch Society of Obstetrics and Gynecology discourages endometrial ablation in women who would like to have a child in the future and emphasizes the need for contraception for all women who undergo endometrial ablation [26]. The British Society of Gynecological Endoscopy takes a similar position and recommends offering laparoscopic sterilization at the time of endometrial ablation [27]. With the introduction of second-generation techniques, endometrial ablations are frequently performed in an office setting. In a recent retrospective analysis including 100 cases, women underwent a combined procedure of NovaSure® ablation and Essure sterilization in an outpatient setting. The procedure was successful in 92% of the cases with a mean duration of the procedure of 17 minutes [28].

## Conclusion

NovaSure® is not a contraceptive. Data on pregnancies after the NovaSure® procedure are still limited. However, the two cases presented here emphasize the need for contraception after NovaSure®. A high complication rate is reported for pregnancy after endometrial ablation. Therefore, contraception is univocally recommended for all women who undergo NovaSure® endometrial ablation. In addition, women with heavy menstrual bleeding who would like to preserve their fertility are not considered to be candidates for endometrial destruction. Vice versa, women who desire to have a child after NovaSure® should be strongly discouraged from becoming pregnant or counseled regarding the high rate of complications and the likelihood of serious consequences for their health and the health of the baby if conception has already occurred.

## References

- Marret H, Fauconnier A, Chabbert-Buffet N, Cravello L, Golfier F, et al. (2010) Clinical practice guidelines on menorrhagia: management of abnormal uterine bleeding before menopause. *Eur J Obstet Gynecol Reprod Biol* 152: 133-7.
- Lethaby A, Penninx J, Hickey M, Garry R, Marjoribanks J (2013) Endometrial resection and ablation techniques for heavy menstrual bleeding. *Cochrane Database Syst Rev* doi: 10.1002/14651858.CD001501.pub4.
- Bhattacharya S, Middleton LJ, Tsourapas A, Lee AJ, Champaneria R, et al. (2011) Hysterectomy, endometrial ablation and mirena for heavy menstrual bleeding: A systematic review of clinical effectiveness and cost-effectiveness analysis. *Health Technol Assess* 15: 1-252.
- Gallinat A, Nugent W (2002) NovaSure impedance-controlled system for endometrial ablation. *J Am Assoc Gynecol Laparosc* 9: 283-9.
- Daniels JP, Middleton LJ, Champaneria R, Khan KS, Cooper K (2012) Second generation endometrial ablation techniques for heavy menstrual bleeding: Network meta-analyses. *Brit Med J* 23: 344.
- Gimpelson RJ (2014) Ten-year literature review of global endometrial ablation with the NovaSure® device. *Int J Womens Health* 6: 269-80.
- Xia E, Li TC, Yu D, Huang X, Zheng J, et al. (2006) The occurrence and outcome of 39 pregnancies after 1621 cases of transcervical resection of endometrium. *Hum Reprod* 21: 3282-6.
- Pugh CP, Crane, JM, Hogan TG (2000) Successful Intrauterine Pregnancy after Endometrial Ablation. *J Am Assoc Gynecol Laparosc* 7: 391-4.
- Roy KH, Mattox JH (2002) Advances in Endometrial Ablation. *Obstet Gynecol Surv* 57: 789-802.
- Yin CS (2010) Pregnancy after hysteroscopic endometrial ablation without endometrial preparation: a report of five cases and a literature review. *Taiwan J Obstet Gynecol* 49: 311-9.
- Hare AA, Olah KS (2005) Pregnancy following endometrial ablation: a review article. *J Obstet Gynaecol* 25: 108-14.
- Roux I, Das M, Fernandez H, Deffieux X (2013) Pregnancy after endometrial ablation. A report of three cases. *J Reprod Med* 58: 173-6.



13. Smith SE, Bacher-Lind L (2012) Pregnancy Outcomes Following a Novasure® Endometrial Procedure. *J Minimal Invas Gynecol* 19: 21.
14. Holt R, Santiago-Munoz P, Nelson DB, Twickler D (2013) Sonographic Findings in Two cases of Complicated Pregnancy in Women Previously Treated with Endometrial Ablation. *J Clin Ultrasound* 41: 566-9.
15. Murray A, Williams A, Love C (2014) PPO.59 'Clip it or snip it before you ablate it' beware the pregnancy following endometrial ablation. A Case Report of antenatal uterine rupture with placenta percreta. *Archives of disease in childhood. Fetal Neonatal edn* 99: A169.
16. U.S. Food and drug administration (2014) Protecting and promoting your health. MAUDE adverse event report: Cytoc corp. NovaSure impedance controlled ea system.
17. Longinotti MK, Jacobson GF, Hung YY, Learman LA (2008) Probability of Hysterectomy After Endometrial Ablation. *Obstet Gynecol* 112: 1214-20.
18. Kayem G, Davy C, Goffinet F, Thomas C, Clément D, et al. (2004) Conservative Versus Extirpative Management in Cases of Placenta Accreta. *Obstet Gynecol* 104: 531-6.
19. Nybo Andersen AM, Wohlfahrt J, Christens P, Olsen J, Melbye M (2000) Maternal age and fetal loss: population based register linkage study. *BMJ* 320: 1708-12.
20. Beck S, Wojdyla D, Say L, Betran AP, Merialdi M, et al. (2010) The worldwide incidence of preterm birth: a systematic review of maternal mortality and morbidity. *Bulletin World Health Organization* 88.
21. Moretti F, Merzotis M, Ferraro ZM, Oppenheimer L, Fung KFK (2014) The importance of a Late First Trimester Placental Sonogram in Patients at Risk of Abnormal Placentation. *Cas Rep Obstetrics Gynecol*
22. Vinograd A, Wainstock T, Mazor M, Beer-Weisel R, Klaitman V, et al. (2014) Placenta Accreta Is An Independent Risk Factor For Late Pre-Term Birth And Perinatal Mortality. *J Matern Fetal Neonatal Med* 18: 1-7.
23. Conroy K, Hsieh F, Craig S (2014) Spontaneous uterine rupture from placenta percreta: An increasing phenomenon? *Obstet Gynecol* 123: 142s-3s.
24. Shamshirsaz AA, Fox KA, Salmanian B, Diaz-Arrastia CR, Lee W, et al. (2014) Maternal morbidity in patients with morbidly adherent placenta treated with and without a standardized multidisciplinary approach. *Am J Obstet Gynecol* 212: 218.
25. O'Brien, Barton JR, Donaldson ES (1996) The management of placenta percreta: Conservative and operative strategies. *Am J Obstet Gynecol* 175: 1632-8.
26. Hehenkamp WJK, Reekers JA, Ankum W, Coppus SFPJ, Janssen CAH et al. (2013) Guidelines for heavy menstrual bleeding. Dutch Society of Obstetrics and Gynecology.
27. Lewis BV (1994) Guidelines for endometrial ablation. *British Society of Gynaecological Endoscopy. Br J Obstet Gynaecol* 101: 470-3.
28. Mircea CN, Goojha C, Thiel JA (2011) Concomitant Novasure Endometrial Ablation and Essure Tubal Sterilization: A Review of 100 Cases. *J Obstet Gynaecol Can* 33: 361-6.

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